EXHIBIT 53

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6004

January 9, 2007

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Divya Patel, President
Actavis Totowa, LLC
101 East Main Street
Little Falls, New Jersey 07424

FILE NO.: 07-NWJ-06

Dear Mr. Patel:

On July 10, 2006, through August 10, 2006, the U.S. Food and Drug Administration conducted an inspection of your facility located at 101 East Main Street, Little Falls, New Jersey. During the inspection, our investigators documented significant deviations from the current Good Manufacturing Practice (cGMP) regulations set forth in Title 21, *Code of Federal Regulations*, Parts 210 and 211, in conjunction with your firm's manufacture of prescription drug products.

The inspection revealed that drug products manufactured in your facility are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform with cGMPs, to assure that such drug products meet the requirements of the Act. The deviations were presented to your firm on a FDA-483, List of Inspectional Observations, at the close of the inspection on August 10, 2006.

The significant observations included, but were not limited to, the following:

1. Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.

Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.

Numerous instances were observed where manufacturing process deviations occurred and in-process specifications were not met, yet there is no indication that action was taken promptly to investigate or to correct the deviations and the products were approved for release and distribution by your quality control unit. Additionally, instances were noted where your firm's quality control unit reviewed and approved test data and reports that were inaccurate and incomplete, and as such, did not follow established procedures. [21 CFR 211.22(a) and 21 CFR 211.22(d)]

Specific examples of the above cGMP deviations were included on the FDA 483 issued to your firm on August 10, 2006, and examples are included in the observations that follow.

2. Our investigators observed that laboratory notebooks did not include all raw test data generated during testing and that analysts do not always document the preparation and testing of samples in their notebooks at the time they are done. Instances were found where analysts aborted and failed to complete chromatographic testing runs after an out-of-specification test result was obtained. The chromatographic test data reflecting the out-of-specification test results were not recorded in laboratory notebooks. Instead, a new sample preparation was injected within the same chromatographic run without supervisory approval, as required by your firm's SOP QC-59, "Investigation of Out of Specification (OOS) Results."

Our investigators also uncovered numerous instances where out-of-specification test results obtained during the testing of your firm's drug products were not adequately investigated. Instead, additional testing was conducted and the original results were discarded without any documented justification. [21 CFR 211.194(a)(4) and 21 CFR 211.160(b)] The following are a few examples:

a) On January 11, 2006, during content uniformity testing of [redacted] batch [redacted] the analyst noticed that the first two capsules were out-of-specification and the run was aborted. The audit trail for the laboratory data acquisition system does not indicate that the run was aborted and the analyst did not print the sample results or record the failing results in the laboratory notebook. An investigation was initiated and it concluded that a sample dilution error was made. A review of the laboratory notebook shows the sample dilution value in the laboratory notebook was overwritten.

without being signed and dated. Additionally, there were differences between the lab notebook page showing the sample preparation and a photocopy of the same page in the investigation. Changes were made in the laboratory notebook after it was signed and approved.

b) The original result of [redacted] for Sample 1-1 for [redacted] and batch [redacted] was not documented in Laboratory Notebook 700-34, and was not attached to the hard copy chromatograms. An additional injection was made for Sample 1-1 within the same chromatographic run and the new results were used in the calculations.

c) [redacted] batch [redacted] was tested on May 31, 2006, and failed to meet the specification for impurities. A new sample preparation was prepared and the batch was retested within the same chromatographic run, without prior approval as required. The original out-of-specification results for high impurities were invalidated without any scientific justification and the batch was released based on the retest results.

3. There was a failure to check for accuracy the inputs to and outputs from the "Total Chrom Data Acquisition System," which is used to run your firm's HPLC instruments during analysis of drug products. For example, electronic data files were not routinely checked for accuracy and, as mentioned in the above observations, our investigators found numerous discrepancies between the electronic data files and documentation in laboratory notebooks. [21 CFR 211.68(b)]

4. Our investigators observed numerous instances where your firm's quality control unit either ignored or failed to recognize that some tablets that did not meet in-process specifications. Additionally, the failure to meet in-process specifications during tablet compression operations was not always documented in production records and there is no indication that the process deviations were promptly corrected during compression operations to avoid releasing tablets that did not have their appropriate quality. Instead, our investigators found instances where compression problems were documented in investigation reports several weeks after they occurred. [21 CFR 211.192] For example:

a) On November 11, 2005, during the compression of [redacted] one tablet was documented as having a hardness value of 8.9 kp. The tablet hardness specification is 10.0-18.0 kp. Additional tablets were not tested to determine the extent of the batch that did meet specifications, as required by your firm's SOP QA-16. There is no indication that any corrective action was taken. The out-of-specification tablet was discovered by your firm on April 26, 2006, during the compilation of data for the Annual Product Review.

b) On October 26, 2005, [redacted] batch [redacted] were observed to contain black specks during tablet inspection. Investigation [redacted], dated November 9, 2005, states under the heading "Employee Interviews," that during tablet compression the operators observed the product sticking to the punch tips. The operator was instructed by the supervisor to remove and clean the upper and lower punches, polish the punch tips, and remove and clean the dies and feed frame. This was not documented during production on the "Compression Data Sheet." The investigation report indicates that the product continued sticking to the punches throughout the remainder of the compression run. This batch was released.

c) On May 19, 2006, during the compression of [redacted] batch [redacted] operators were unable to achieve the target hardness value of 9.0 kp and the tablets were compressed below the action limit of 7.0 kp. The "Compression Data Sheet" for this batch does not include any documentation of problems with the compression run. Although tablet hardness limits were not met, the compression log shows that the compression was approved by Quality Assurance. An investigation was not initiated until June 2, 2006, when the batch did not meet yield specifications. The low yield was attributed to broken tablets. This batch was released.

5. Your firm lacked adequate procedures for conducting bulk product holding time studies. For the following products, the bulk holding time studies initially were generated from the testing of finished products instead of from samples of bulk products held for the holding time studies: [redacted] [21 CFR 211.111]

6. Your firm failed to identify and control rejected in-process materials to prevent their use in manufacturing or processing operations. For example, according to your firm's investigation reports, the batches listed below were rejected because they failed to meet blend uniformity or dissolution specifications. Yet our investigators observed that the batches were stored in your work-in-progress warehouse labeled as in-process materials. [21 CFR 211.110 (d)]

a) [redacted] batch [redacted]
b) [redacted] batch [redacted]
c) [redacted] batches [redacted]

7. Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example:

a) Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: [redacted] Digoxin Tablets, USP, 0.25mg.

b) Recovery studies were performed for numerous drug products by applying a known amount of active pharmaceutical ingredient directly to a swab, instead of applying the active to a coupon or template which would replicate the equipment surface from which the active pharmaceutical ingredient should have been swabbed. The products involved, included: [redacted]

c) Cleaning validation studies do not indicate whether a cleaning agent was used when cleaning the equipment process train. Equipment cleaning SOPs prior to March, 2006, indicated that equipment could be cleaned "using hot water or approved cleaning agent and water if necessary."

8. Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly. [21 CFR 211.186(b)(9) and 21 CFR 211.188(b)(10)]

9. Equipment used in the manufacture of [redacted] and other drug products was not adequately qualified. [21 CFR 211.63] For example:

a) The re-qualification of the Stokes BB2 Tablet Press, Equipment ID 70, which was used in the production of [redacted] batch [redacted], did not have clearly defined acceptance criteria. In addition, there was no discrepancy report to explain why equipment drawings, equipment schematics, equipment manuals, and purchase orders were not available, what steps had been taken in an attempt to obtain these materials, and why the re-qualification was acceptable without this information.

b) The specified utility requirements were not met in the equipment re-qualification for Fitzmill ID 12, which was used in the production of [redacted] batch [redacted]. There is no discrepancy report to explain why this failure to meet the specification is or is not acceptable.

c) There were no equipment qualifications for the Lydon Brothers, Inc., Drying Oven ID # 271 or the Blue M Drying Oven ID 273. These ovens are used in the production of [redacted] as well as more than [redacted] other drug products.

10. There were failures to establish and follow written procedures for maintenance of manufacturing equipment. [21 CFR 211.67] For example:

a) Duct tape was observed on the feed throat of Fitzmill 12. It appeared that the duct tape was being used to prevent powder from escaping through the feed throat during production.

b) Although your firm has a maintenance log showing the replacement of equipment parts, there was no procedure for the routine maintenance of Lydon Brothers Drying Oven ID 271 or the Blue M Drying Oven ID 273.

c) Although according to your firm's procedure, "PRD-011: Blenders - Preventative Maintenance and Repairs," preventative maintenance is to be conducted on double cone blender ID 41 every six months, no maintenance had been conducted between January 8, and December 8, 2004, or between May 12, 2005, and May 19, 2006.

We have reviewed the corrective actions promised in your letter dated August 29 and 30, 2006, as well as in your update reports dated October 18, 2006 and November 17, 2006. Additionally, we have reviewed your firm's Quality System Improvement Plan (QSIP) dated October 18, 2006. Although your August 29 and 30, 2006, letter disagrees with several specific observations listed on the August 10, 2006, FDA 483, your November 17, 2006, letter states that all observations listed on the FDA 483 are "correct and constructive," and that your firm has identified the need for improvements in operational procedures and practices at the Actavis Totowa Little Falls, NJ facility. In fact, we do not agree with assertions in your August 29 and 30, 2006, letter that certain of the observations listed on the FDA 483 are not accurate.

While the corrections that you promise in your correspondence appear to adequately address many of the cGMP deviations found during the July 10 through August 10, 2006, inspection, we are concerned about the quality of drug products that have been released from your facility under the serious lack of cGMP controls found during the inspection. Your response provides no assurance that the records and conditions of manufacture and testing of each such lot of drug products released and marketed by your firm will be evaluated to assure that the released drug products have their appropriate identity, strength, quality, and purity. We feel that to provide such assurance, your firm should promptly initiate an audit program by a third-party having appropriate cGMP expertise, to provide assurance that all marketed lots of drug products that remain within expiration have their appropriate identity, strength, quality, and purity.

Please provide us with a listing of all released lots of finished drug products that remain within expiration that are associated with any out-of-specification test results during their manufacture and provide a brief description of the actions taken to ensure that the lots were suitable for release.

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. Additionally, FDA may withhold approval of requests for export certificates, or approval of pending new drug applications listing your facility as a manufacturer until the above violations are corrected. A reinspection may be necessary.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. If you no longer manufacture or market any of your products, your response should so indicate, including the reasons for, and the date on which, you ceased production.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer. Please note, the agency will be replying separately to your firm's responses dated September 6, September 11, October 18, and November 1, 2006, to the August 15, 2006 warning letter.

Very truly yours,

Douglas I. Ellsworth
District Director
New Jersey District Office

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